UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,262	07/18/2003	Arnaud Mainnemare	1254-03	4220

35811 7590 02/08/2007

IP GROUP OF DLA PIPER US LLP
ONE LIBERTY PLACE
1650 MARKET ST, SUITE 4900
PHILADELPHIA, PA 19103

EXAMINER	
KIM, JENNIFER M	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,262	MAINNEMARE, ARNAUD	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-19,21,23 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,22,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/15/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group III (claims 20, 22, 25 and 26) drawn to a method for treatment and/or preventing viral infections, and/or fungal infections, and/or diseases generated from non conventional transmissible agents, in humans or animals and a method of modulating immunity in humans or animals comprising administering to a human or animal a pharmaceutically effective amount of a pharmaceutical composition comprising: at least one halogenated compound, and at least one-N-halogenated derivative of at least one compound selected from zwitterionic compounds and/or amino acids or their derivatives, without substantial stimulation of myeloperoxidase activity in the human or animal, classified in class 252 subclass 187.26; class 514, subclass 561is acknowledged. The traversal is on the ground(s) that there is no burden on the Patent Office to consider all of the claims together because all of the claims fall within the same classes and subclasses. This is not found persuasive because the claims are drawn to various number of unrelated methods and compositions with materially different process involving different biological pathway with unrelated known treatments; searches are not coextensive, particularly required non-patent literature search would place a serious burden on the examiner. Therefore, the restriction requirement made on the last Office Action is deemed proper and made final.

The Examiner thanks Applicant for correctly pointing out an inadvertent error on the grouping of claims 25 and 26 with Group IV, rather than with Group III. Accordingly,

claims 25 and 26 is being included and examined with claims 20 and 22 (elected Group III).

Claims 1-19, 21, 23 and 24 are withdrawn from consideration because they are non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written description

Claims 20, 22, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention.

Claims 20, 22, 25 and 26 are drawn to a method for treatment and/or preventing various infections comprising administering at least **one halogenated compound.** The claims thus encompass a broad genus of a **halogenated compound**.

The instant specification does not describe or exemplify all halogenated compounds, much less a structural moiety to identify any compounds qualified as a

halogenated compound. Accordingly, the instant specification does not provide a basis for one of skill in the art to envision the structural/functional characteristics of such compounds. The premise for the limitation of a halogenated compound appears to be derived from the observation in the instant specification of a single halogenated compound (sodium hypochlorite). The specification does not however, indicate why one should assume based on the disclosure of the employment of a single halogenated compound (sodium hypochlorite) that any species of the broad genus of a halogenated is represented without identifying the chemical structural moiety related to the compounds. Given this lack of description of a sufficient number of the representative species encompasses by the genus of the claim, the specification fails to described the claimed invention in such full, clear, concise, and exact terms regarding the chemical structure-function relationship that a skilled artisan would not recognize that Applicants were in possession of the claimed invention, "halogenated compound".

Claims 20, 22, 25 and 26 are drawn to a method for treatment and/or preventing **disease generated from non conventional transmissible agents** administering at least one halogenated compound and least lest one N-halogenated derivative. The claims thus encompass treatment of a broad genus of **diseases generated from non conventional transmissible agents** and a broad genus of **non conventional transmissible agents.**

The instant specification does not describe the specific symptoms, lab findings, target cells, detection tests, clinical findings or differential diagnosis to reasonably

convey the broad genus of **diseases** generated from non conventional transmissible agents.

The instant specification does not describe or exemplify **non conventional transmissible agents**, much less a structural moiety/physical/chemical characteristics in order to identify any agents qualified as a non conventional transmissible agent.

Given these lack of description of a sufficient number of the representative species of **non conventional transmissible agents** and **a disease** generated form the agents encompasses by the genus of the claims, the specification fails to described the claimed invention in such full, clear, concise, and exact terms regarding the chemical structure-function relationship that a skilled artisan would not recognize that Applicants were in possession of the claimed invention, "**diseases generated from non conventional transmissible agents**" and "**non conventional transmissible agents**".

Enablement

1. Claims 20 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treatment" of various infections, does not reasonably provide enablement for the "**prevention**". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

2. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the

specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of treating and/or **preventing** viral infections, and/or bacterial infections, and/or parasitical infections, and/or fungal infections, and/or diseases generated from non conventional transmissible agents, in humans or animals comprising administering to a human or animal comprising administering to a human or animal a pharmaceutically effective amount of a pharmaceutical composition comprising: at least on halogenated compound, and at least one N-halogenated derivative of at least one compound selected **from zwitterionic compounds and/or the amino acids or their derivatives. The nature of the invention is extremely complex in that it encompasses the actual prevention** of various infections such that the subject treated with above compounds does not contract any infection.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass **prevention** of a complex cell proliferation disorder in humans which has potentially many different causes (i.e. many different mutations or combination of mutations; various microorganisms, virus etc.). Each of which may or may not be addressed by the method comprising administration of the composition.

Guidance of the Specification: The guidance given by the specification as to how one would administered the claimed compounds to a subject in order to actually **prevent** various inventions involving different microorganism is minimal. All of the guidance provided by the specification is directed towards treatment rather than prevention of various infections.

Working Examples: All of the working examples provided by the specification are directed toward the treatment rather than **prevention** of various infections.

State of the Art: While the state of the art is relatively high with regard to treatment of infections involving specific microorganism (i.e. *streptococcus* infected throat), the state of the art with regard to prevention of such disorders is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed compounds was administered to a subject to **prevent** development of various infections. The state of the art, Cecil Text Book of Medicine 21st edition, page 1814, left-hand column, under Prevention, states that at present, there are no licensed vaccines directed against SHV (Herpes Simplex Virus) for the prevention.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual prevention of various infections in a human subject with the claimed composition makes practicing the claimed invention unpredictable in terms of **prevention** of various infections.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of

appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for **prevention** of various infections. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard prevention of various infections with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding **prevention** of various infections with any compound, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention **to prevent** the development of infection in a subject by administration of one of the claimed compositions.

Therefore, a method of treating and/or **preventing** viral infections, and/or bacterial infections, and/or parasitical infections, and/or fungal infections, and/or diseases generated from non conventional transmissible agents, in humans or animals comprising administering to a human or animal comprising administering to a human or animal a pharmaceutically effective amount of a pharmaceutical composition comprising: at least on halogenated compound, and at least one N-halogenated

derivative of at least one compound selected from zwitterionic compounds and/or the amino acids or their derivatives is not considered to be enabled by the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 22, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "derivatives" in claims 20 and 22 are indefinite because it is not clear what are the compounds that are actually qualified as such. One of ordinary skill in the art could not ascertain and interpret the metes and bounds of the term "derivatives" of zwitterionic compounds and/or the amino acids, since one of ordinary skill in the art would clearly recognize that "derivatives" of those compounds in the claims could read on any zwitterionic compounds and/or the amino acids having widely varying groups that can be a substituents of the compounds. It is noted that the specification does not describe any chemical structures or substituents to be employed and there is no clear structural limitation showing what are substituents/modifications to the zwitterionic compound and/or the amino acids can be employed in the instant application. Accordingly, one of ordinary skill in the art would not be able to practice the employment of the "derivatives" instantly claimed.

The "non conventional transmissible agents" is indefinite because it is not clear what are the non conventional transmissible agents would generate diseases. The specification does not describe any requisite or qualifications in order identify the non conventional transmissible agents. One of ordinary skill in the art would not be able to practice the invention because one could not ascertain and interpret the metes and bounds of the "non conventional transmissible agents".

With regard to claims 25 and 26, the term "linked" to is not clear how the lesions and infections are "linked" with the disorders. Is it that the lesions and infections are "linked" as they are **caused by** the diseases (periodontitis or herpesviridae); or is it that diseases (periodontitis or herpesviridae) are "linked" as they cause lesions and infections?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20, 22, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Julich et al. (1993).

Julich et al. teaches that chloramine T (taurine chloramine) and Sodium hypochlorite (NaOCl) both have antiviral activity. (page 310, Table 3). Julich et al. teach that due NaOCl's excellent compatibility with various materials, it may be used for the disinfecting dentures. (page 311 right-hand side second full paragraph).

Julich et al. do not teach the combination of Chloramine T and NaOCl for the treatment of infections, particularly, viral infection and the mechanism of action of substantial stimulation of myeloperoxidase activity in the human or animal and infections linked or caused by the disorders set forth in claims 25 and 26.

It would have been obvious to one of ordinary skill in the art to combine sodium hypochlorite and chloramine T in a single composition for the treatment of various infections including viral infection because each of the active agents to be utilized are effective for the treatment of infections having antiviral activities including HSV (herpesviridiae) and HBV. One would have been motivated to combine sodium hypochlorite and chloramine T in a single formulation for the treatment of virus infection regardless of the cause in order to achieve at least an additive effect of having anti viral effect in treatment of viral infection. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Further, the mechanism of action of without substantial

stimulation of myeloperoxidase activity in the human or animal is obviously achieved by the obvious modification involving same active agents for the same treatment.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
February 5, 2007